

## REMARKS

### The Claim Amendments

Applicant confirms the withdrawal of claims 51-56. This withdrawal is made expressly without waiver of applicant's rights to pursue any canceled subject matter in divisional or other related application(s) claiming benefit from this application.

Applicant has amended claims 45 and 46 to recite a method for identifying environmental parameters of interest by providing an environmental sample and deleting reference to a soil sample. Support for this claim amendment can be found, e.g., at page 17, lines 7-25, page 7, lines 20-27, page 13, lines 19-22, and in claims 43 and 44 of the specification as originally filed.

Claims 45-50 are now pending in this application.

### Office Action

### Election/Restriction

The Examiner acknowledged applicant's election with traverse of species B (the environmental parameter of interest is a natural gas deposit). Applicant thanks the Examiner for reconsidering the restriction and agreeing that species A (a subsurface oil) and B (a natural gas deposit) should be examined together. She has withdrawn claims 51-56 as being drawn to a non-elected species and has examined claims 45-50 on the merits.

### Information Disclosure Statement

Applicant acknowledges the Examiner's consideration of the documents submitted in the April 14, 2004 Information Disclosure Statement.

Claim Interpretations

The Examiner has interpreted the term “PCR-based assay” as any assay utilizing PCR in any step. Applicant traverses.

As taught in the specification and as recited in the pending claims, the term “PCR-based assay” is a diagnostic assay that uses species-specific probes, identified from markers with a robust correlation to a sample parameter of interest, *as a diagnostic or to prospect for the parameter of interest* in the DNA isolated from the sample. See, page 27, lines 25-27 of the specification as filed. In the present invention, these DNA sequence-specific probes that correlate with the desired parameters of the various samples serve as the basis for the claimed high throughput quantitative diagnostic assays. The diagnostic PCR-based assay of this invention, thus, does not consist of merely any assay that uses PCR in any step.

The Examiner has interpreted the term “parameter of interest is surface oil or natural gas deposit” as any area containing oil or gas. Applicant agrees with this term interpretation.

The Examiner has interpreted the terms “perfect correlation” and a “high degree of correlation” as being equivalent, and has interpreted a “moderate degree of correlation” as having any degree of correlation. Applicant traverses in part.

A perfect correlation is distinct from a high degree of correlation. As taught in the specification on page 29, lines 8-14, a perfect degree of correlation has an  $r$  of 1.0. A high degree of correlation has an  $r$  of between 0.8-0.99. The two are therefore not equivalent.

Rejections

35 U.S.C. §102(b) - Anticipation

Claims 45-50 stand rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Telang et al., Can. J. Microbiol., vol. 40, 955-964, 1994 (“Telang”). According to the Examiner, Telang refers to a method of identifying environmental parameters of interest by providing soil samples containing microbial populations, isolating DNA from the soil samples and performing a hybridization assay using “species-specific” and “total genomic” probes. The Examiner contends that Telang further infers the presence of sulfur-reducing bacteria in samples using NiFe hydrogenase gene probes and 16S rRNA probes. More particularly, the Examiner asserts that Telang teaches a high degree of or perfect correlation between the hybridization to the probes and the presence of sulfur-reducing bacteria in soil and, moreover, that sulfur-reducing bacteria are associated with oil and gas fields. Applicants traverse.

- Applicant’s invention and Telang are totally different. Applicant’s invention is based on creating profiles of microbial diversity from samples and analyzing the profiles to correlate the presence of nucleic acid markers with desired parameters in a sample. See, page 1, Technical Field of the Invention. The methods of the invention, thus, comprise identifying and using specific DNA sequences as molecular indicators, wherein the presence or abundance of these indicators correlates with a parameter of interest. More particularly, claim 45 and the claims that depend therefrom are directed to methods of identifying environmental parameters of interest by performing a diagnostic PCR-based assay using probes that correlate to the desired parameter.

By contrast, Telang does not teach or suggest the use of the claimed diagnostic assay. Rather, Telang uses PCR solely to create a reagent to perform a hybridization assay. This does not comprise the use of a PCR-based assay diagnostically, as taught in the present specification and claimed in the pending claims. *See supra*, Claim Interpretations.

Applicant, for example, teaches that species-specific probes, for markers with a robust correlation to a sample parameter of interest, are used as a diagnostic for the parameter of interest. The species-specific probes are prepared from and are characteristic of the DNA sequences of the markers. See, page 27, lines 15-24. In other words, applicant's species-specific probes are based on and serve as detection means for the presence of a marker having a significant correlation with a sample parameter of interest. See, e.g., page 27, lines 20-22.

Telang does not teach or suggest the use of a species-specific probes. Rather, Telang teaches that the NiFe hydrogenase gene probe is genus-specific. See, page 957 of Telang (stating that “[g]enomes from SRB of the genus *Desulfovibrio* have been shown to hybridize with the [NiFe] hydrogenase gene probe, while those of SRB from other genera do not.”)

The NiFe probes used in Telang are genus-specific and thus do nothing in the way of distinguishing the samples. There are no bands in common at all between the different sample types. See, Table 2, Southern column of Telang. Moreover, Telang's 16S rRNA probes are also not species-specific and do not serve to distinguish the samples, as they hybridize to something in every sample. See, Table 2, Code column of Telang. In the Results section of Telang, on page 957, it states that “many preparations gave hybridization patterns that were either highly complex (indicative of the presence of genomic DNAs from multiple species) or nondistinct

(owing to lack of digestion or DNA degradation)”, thereby further verifying the non-species-specific nature of the Telang probes.

Moreover, and in relation to the use of species-specific probes, claims 45-50 are directed to performing a diagnostic PCR-based assay utilizing a plurality of species-specific probes to the nucleic acid marker sequence that shows a correlation to the parameter of interest. Telang does not teach or suggest the use of species-specific probes or a plurality of such probes and also does not show a correlation between species-specific probes and the nucleic acid marker sequences and the parameter of interest. Telang has established a diversity profile, but has not further characterized it or correlated it with a parameter of interest. Telang entirely ignores applicant’s step of identifying the species and species-specific probes to establish a correlation between a marker and a sample parameter of interest.

The Examiner contends that the NiFe and 16S probes teach a high degree of correlation between the hybridization and the presence of sulfur-reducing bacteria, which are found in oil and gas formation. This is circular. If the probes hybridize then their sequences are present in the samples, but Telang does not show that there are sulfur-reducing bacteria by any means other than their probes. Nor does Telang demonstrate the absence of sulfur-reducing bacteria where no hybridization occurs. The hybridization of the 16S probe cannot correlate with the presence of oil or gas, because it is present in every sample and the patterns (as shown by the pattern ID No. after the first 5 letters in the Code column of Telang’s Table 2) correlate only to samples from the same location rather than to different samples with common properties (i.e., the presence of oil or gas). Thus, Telang does not teach or suggest the use of any species-specific probes that correlate with any single parameter of interest.

Appln. No. 10/607,077

Response dated August 31, 2006

Response to Office Action dated May 31, 2006

For these reasons, Telang does not anticipate the pending claims under 35 U.S.C.

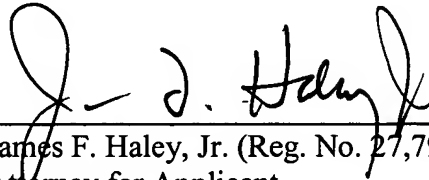
§ 102(b). Accordingly, applicant requests that the rejection be withdrawn.

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Conclusion

Applicants request favorable consideration and early allowance of the pending claims.

Respectfully submitted,



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